

[0094] The characteristic meter **300** utilizes test strips **350**, or the like, with a sample obtained from the body of the patient to determine a characteristic (or analyte level) in a user at a discrete point in time. The discrete measurement from the characteristic meter **300** is stored in a memory of the medical device module **200** and may be used to calibrate the characteristic monitor **200'** in the medical device module **200** against the test results from the characteristic meter **300**, either in real time or using a post calibration in either the characteristic monitor **200'** in the medical device module **200** or during later analysis and review once the test results have been downloaded to a separate computer, communication station, or the like. Possible characteristic meters **300** that may be used are produced by Roche Diagnostics, Bayer Corporation, Abbott Medisense, Johnson & Johnson, Mercury Diagnostics, Chronimed, or the like.

[0095] FIG. 5 illustrates a simplified flow block diagram of the medical device module **200** shown in FIGS. 4 and 6. As shown in FIG. 5, the medical device module **200** includes the characteristic meter **300** and also the characteristic monitor **200'** that interfaces with a sensor set **150**. The medical device module **200** includes a keypad interface **202**, a ROM **204**, a RAM **206**, a display interface **208**, a data Input and Output (I/O) port **210** that uses the contacts **222** on the medical device module **200** to connect with the contacts **122** on the PDA **10**, a sensor monitor **212**, a sensor interface **214**, a microprocessor **216**, and a battery and/or power supply **218**. An overlapping subset of these elements is used to process the data from the sensor **150** and is collectively shown as the characteristic monitor **200'**. The characteristic meter **300**, included in the medical device module **200**, includes a characteristic test meter **302** and a test interface **304**.

[0096] The microprocessor **216** of the medical device module **200** is activated in several different ways. The keypad interface **202** is coupled directly to the microprocessor **216** and is useable to activate the microprocessor **216** upon activation of the keys **106** and **108** and/or display **102** of the PDA **10**. The microprocessor **216** is then prepared to store relevant information concerning the sensor data, meter readings, event data, or the like. For instance, the microprocessor **216** will store, the time, the date and the analyte level from a test strip **350** or may be used to record an independent event by the user. In addition, the keypad interface **202**, unpin interfacing with the PDA **10**, may be used to activate and control the microprocessor **216** to perform analysis, calibration, control the display interface **208** and display **102**, download stored data and results, upload program instructions, or the like. The microprocessor **216** may also be activated by receiving a specified signal from the sensor interface **214** indicating connection or receipt of data from a sensor **150** and/or by insertion of a test strip **350** into the test interface **304** of the included characteristic meter **300**. Once activated, the microprocessor **216** stores data, analyzes signal values, tests results for accuracy, calibrates, downloads data, presents data for review and analysis, provides instructions, warnings and alarms, or the like.

[0097] The microprocessor **216** is coupled to a ROM **204** and a RAM **206**. In preferred embodiments, the ROM **204** is an EPROM and the RAM **206** is a static RAM; however, other comparable memory storage components such as dynamic RAM, non-static RAM, rewritable ROMs, flash

memory, or the like, may be used. Generally, the ROM **204** stores the programs used by the microprocessor **216** to determine various parameters, such as the amount of an analyte corresponding to a received signal value in the sensor monitor **212** signal value, calibration techniques for adjusting the sensor signals from the sensor **150**, characteristic meter **300** operation and correspondence of test results with the sensor signal values, the date and the time, and how to report information to the user. The RAM **206** is used by the microprocessor **216** to store information about the sensor signal values and test strip **350** test results for later recall by the user or the doctor. For example, a user or doctor can transcribe the stored information at a later time to determine compliance with the medical regimen or a comparison of analyte value levels to medication administration. This is accomplished by downloading the information to the display **102** through the display interface **208** and then transcribing all of the stored records at one time as they appear on the display **208**. In addition, the RAM **206** may also store updated program instructions and/or patient specific information.

[0098] In preferred embodiments, the microprocessor **216** is coupled to a data input and output (I/O) port **210** that uses the contacts **222** on the medical device module **200** to connect with the contacts **122** on the PDA **10**, and the user can download the stored information to an external computer (see FIG. 1), or the like, through the data I/O port **210** for evaluation, analysis, calibration, or the like. Preferably, the data I/O port **210** is capable of transferring data in both directions so that updated program instructions or reminder alarms can be set by the user or doctor. In preferred embodiments, the I/O port **210** uses the infrared (IR) technology of the PDA **10** or may include its own IR transceivers similar to those shown and described in U.S. Pat. No. 5,376,070 entitled "Data Transfer System for an Infusion Pump", or the like, which is herein incorporated by reference. However, in alternative embodiments, the I/O port **210** may use other data transfer technologies such as cables, fiber optics, RF, or the like. In still other embodiments, the data I/O port **210** may include multiple ports to support multiple communication protocols or methods, or may include a universal port capable of transmitting data in several different modes. In preferred embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) a computer, communication station, or the like. In alternative embodiments, the stored data may be downloaded to (or new program instructions and data uploaded from) an infusion pump, or the like.

[0099] The keypad interface **202** provides the user with the capability to set parameters in the medical device module using the keys **106** and **108** and/or display **102** of the PDA **10**. Such capabilities include, but are not limited to, storing additional information, setting the date and the time, or setting alarms to indicate when to take the next test with the characteristic meter **300**. The keypad interface **202** is used in conjunction with the display interface **208** to access the various modes, alarms, features, or the like, by utilizing methods typically employed to set the parameters on a conventional glucose meter, an infusion pump, or the like. Except this is all done through the use of a standard PDA interface.

[0100] The medical device module **200** also includes a self contained battery and power supply **218**. Preferably, the